

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-418V

UNPUBLISHED

ELLEN M. LUCEY, personal
representative of the Estate of
VALERIAN KOSTKA,

Petitioner,
v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 2, 2024

Special Processing Unit (SPU);
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA); Six Month
Severity Requirement

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 8, 2021, Valerian Kostka filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). The Petition alleges that Mr. Kostka suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccine administered on September 19, 2019. Petition at 1-2.

For the reasons discussed below, I find Petitioner has established that Mr. Kostka suffered the residual effects of his injury for more than six months.

¹ In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Mr. Kostka filed this matter on January 8, 2021. On December 19, 2021, Mr. Kostka passed away, and Ellen M. Lucey was thereafter designated as personal representative of his estate. Ex. 13, 14, ECF Nos. 34, 35.

Respondent filed a Rule 4(c) Report opposing compensation on August 8, 2022. ECF No. 36. Respondent argues (among other things) that Petitioner cannot meet the Vaccine Act's "severity" requirement, and also cannot meet the Table requirements because Mr. Kostka's pain did not occur within 48 hours of vaccination. On December 1, 2022, Petitioner filed a motion for a ruling on the record in favor of the claim. Motion for Ruling on the Record ("Mot."), ECF No. 39. Respondent opposed the motion on February 13, 2023. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 42, at 11-19. Petitioner filed a reply on February 21, 2023. Petitioner's Reply to Respondent's Response to Motion for Ruling on the Record ("Reply"), ECF No. 43. The matter is ripe for resolution.

II. Factual Background

The medical records reveal that Mr. Kostka was eighty five years old at the time of vaccination, and had previously suffered from conditions including lower back pain, gait abnormalities, bladder cancer, chronic kidney disease, type II diabetes, peripheral vascular disease, among other conditions. See, e.g., Ex. 2 at 857, 1211, 1268, 1329; Ex. 3 at 14; Ex. 6 at 58-79, `42-43, 125-33; Ex. 9 at 95-97, 282-83.

On September 19, 2019, Mr. Kostka received a flu vaccine in his left arm. Ex. 7 at 2. Four days later, he had a pulmonary consultation for interstitial lung disease. Ex. 10 at 309-89. There is no reference to left shoulder pain at that time. The next day, on September 24, 2019, he went to the emergency room for "gradual onset of progressively worsening pain ever since" his flu vaccination. Ex. 11 at 46. X-rays and an ultrasound was taken, which revealed mild degenerative changes but no thrombosis. *Id.* at 47. Mr. Kostka was diagnosed with acute left shoulder pain. *Id.* at 48.

Mr. Kostka again complained of shoulder pain on September 27, 2019, stating in a message to his primary care provider that he "got [a] flu shot and the pain in [his] shoulder has been bad." Ex. 2 at 461. The same day, Mr. Kostka reported that his shoulder had been painful for approximately five days at a walk-in clinic. Ex. 11 at 49. He was referred to an orthopedic and prescribed prednisone. *Id.* at 53.

On October 2, 2019, Mr. Kostka had an orthopedic consultation with Physician's Assistant ("P.A.") Jeff Ambord, for left shoulder pain. Ex. 11 at 15. Mr. Kostka reported that his pain started "after a flu shot on 9/19/19", that his shoulder began hurting the following day, and by "9/21/19 it had gotten significantly worse." *Id.* An examination showed decreased range of motion and reduced strength. *Id.* at 16. P.A. Ambord expressed the belief that Mr. Kostka was asymptomatic for a rotator cuff tear that had been exacerbated by the flu vaccine. *Id.* at 17. A cortisone injection was administered at that time. *Id.* at 17.

Mr. Kostka returned to P.A. Ambord on October 7, 2019, with continued reports of left shoulder pain and impingement syndrome. Ex. 11 at 20. He reported only one hour of relief from the first steroid injection, and therefore another was administered. *Id.* at 21.

On October 9, 2019, Mr. Kostka had an aquatic physical therapy evaluation for left shoulder pain. Ex. 3 at 16. He saw his primary care physician on October 15, 2019, for ongoing shoulder pain among other problems (including weight loss, weakness, imbalance, loss of appetite, and uncontrolled blood sugars). Ex. 2 at 377, 437. An examination of his shoulder showed restricted range of motion and his diagnoses included muscle weakness, balance problem, anemia, vitamin D deficiency, and left shoulder pain. *Id.*

Mr. Kostka had an annual preventive health screening on October 28, 2019. Ex. 9 at 249. He reported weakness and the "loss [of] use of left arm" following a flu shot, and shoulder pain that started "about 3 days after" vaccination. *Id.* at 255. Mr. Kostka also saw P.A. Ambord on October 28, 2019, for "follow up on his left shoulder with clinically consistent massive cuff tear." Ex. 11 at 9. He noted that Mr. Kostka's range of motion had improved, but his pain had "not changed much." *Id.* An examination of his shoulder revealed reduced range of motion, and P.A. Ambord assessed him with "high clinical suspicion of a massive cuff tear". Ex. 11 at 9-10. P.A. Ambord's plan of care included continued physical therapy for his shoulder, and additional therapy for his "deconditioned state as well as for lower extremity strengthening...." *Id.* at 10.

At his tenth physical therapy session on November 12, 2019, Mr. Kostka was treated for shoulder pain and leg weakness. He reported "only slight pain at [his] posterior shoulder." Ex. 3 at 159. At his next physical therapy session on November 14, 2019, Mr. Kostka reported minimal shoulder pain at rest and focused on his lower extremities and balance. *Id.* at 166.

Mr. Kostka saw Dr. Wayne Brearley, an orthopedist, on December 18, 2019, for left shoulder pain. Ex. 11 at 11. An examination showed reduced range of motion and

strength, and x-rays showed degenerative changes with mild arthritis. Dr. Brearley diagnosed Mr. Kostka with rotator cuff arthropathy and a rotator cuff tear. *Id.* at 14.

On January 2, 2020, Mr. Kostka was discharged from physical therapy after 25 visits due to plateau in progress. Ex. 3 at 9-10. Mr. Kostka reported that his pain was currently “2-3/10” and that he was “getting more comfortable with his [home exercise program]”. *Id.* at 10.

Mr. Kostka had a second physical therapy evaluation on January 7, 2020, for “left shoulder massive rotator cuff tear.” Ex. 11 at 34. He reported that his shoulder pain “is so bad at times he gets sick to his stomach and is not able to eat.” *Id.* Additionally, he reported weakness and reduced range of motion. *Id.* at 35.

On January 28, 2020, Mr. Kostka saw Dr. Pamela Glennon, a new orthopedist, for shoulder pain. Ex. 8 at 25. He reported dull pain through his shoulder “which has improved significantly following [physical therapy].” *Id.*

Mr. Kostka continued to attend physical therapy for both his shoulder and his lower extremities. On March 2, 2020, at a physical therapy session, Mr. Kostka reported his range of motion was back to normal and pain improved to “mild soreness here and there.” Ex. 12 at 5468, 5470.

Mr. Kostka next reported shoulder pain three times in March 2020. Ex. 12 at 4271 (record from March 13, 2020 reporting left shoulder pain levels of “2/10”); 4343 record from March 9, 2020, reporting left shoulder pain levels of “2/10”); 4415 (record from March 6, 2020, reporting mild shoulder pain of “2/10”). By March 16, 2020, however, he denied shoulder pain at a physical therapy session, but reported lower extremity and hip pain. Ex. 12 at 4199. The exercises at that time were focused on Mr. Kostka’s lower extremities. *Id.* at 4199-4200.

Mr. Kostka was discharged from physical therapy on May 22, 2020, due to lack of participation. Ex. 12 at 4099. The record states that “[t]he patient was placed on hold from therapy in early March due to COVID-19 and has not returned for further therapy interventions due to ongoing health issues.” *Id.*

On August 11, 2020, Mr. Kostka was seen for right shoulder problems, but did not mention any left shoulder problems. Ex. 8 at 19, 23. Thereafter, Mr. Kostka sought treatment for various unrelated ailments, including interstitial lung disease and chronic obstructive pulmonary disease, myofascial pain syndrome, a urinary tract infection, sepsis, and hospitalization for respiratory failure. Ex. 5 at 177-80; Ex. 9 at 120-40, 148,

151, 402-87; Ex. 10 at 27-139; Ex. 12-1 at 641-730, 732-38; Ex. 12-3 at 2313-2405, 2412-2483, 2564-65; Ex. 12-4 at 2566-2650.

Mr. Kostka next reported shoulder pain several months later, on February 18, 2021, during a physical therapy session for back pain. Ex. 12 at 1264. He stated that he hurt “all over” with increased pain in the right neck and shoulder and entire arm to the hand, left shoulder, bilateral shins.” *Id.* On April 2, 2021, Mr. Kostka began another course of physical therapy for right sided neck pain. Ex. 12 at 732-38. The records also noted that he had “[n]oted weakness of L[eft] shoulder from rotator cuff impairment.” *Id.* at 734.

Mr. Kostka passed away on December 19, 2021, from bladder cancer, chronic obstructive pulmonary disease, and type II diabetes mellitus. Ex. 13.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.*

In particular, a petitioner must establish that he suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged

signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

In addition to causation, a petitioner must also meet the requirements establishing that the vaccine received is “covered” by the Program, the duration and severity of petitioner’s injury, and the lack of other award or settlement.³ With regard to severity, a petitioner must show that he suffered the residual effects or complications of his injury or condition for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); see *Song v. Sec'y of Health & Hum. Servs.*, 31 Fed. Cl. 61, 65-66 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding solely on medical records. Section 13(a)(1); see *Colon v. Sec'y of Health & Hum. Servs.*, 156 Fed. Cl. 534, 541 (2021). Severity must be established regardless of whether the claim arises under the Table or is a causation-in-fact claim.

A. Severity Requirement

The first issue to be resolved is whether Mr. Kostka has demonstrated that he suffered “residual effects or complications of [the injury alleged] for more than six months after the administration of the vaccine,” as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for his injury. See § 11(c)(1)(A)(B)(D)(E).

There is no dispute that Mr. Kostka received the flu vaccine on September 19, 2019, and he therefore must demonstrate by preponderant evidence that his residual symptoms continued at least through March 19, 2020 (assuming onset of pain the day of vaccination). See, e.g., *Herren v. Sec'y of Health & Human Servs.*, No. 13-100V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); see also *Hinnefeld v. Sec'y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's injury resolved less than two months after onset).

The record establishes that Mr. Kostka consistently reported shoulder pain between September 24, 2019 and March 13, 2020, just one week shy of the six-month post-vaccination date. Ex. 11 at 46, Ex. 12 at 4271. By that later date, he was reporting shoulder pain levels of two out of ten. Ex. 12 at 4271. Further, the records explain that Mr. Kostka's physical therapy was subsequently halted due to COVID-19 and ongoing health issues. Ex. 12 at 4099.

Based on the foregoing, Respondent argues that Mr. Kostka only sought treatment for shoulder pain approximately five months after vaccination, and thereafter focused on other complaints such as strength and balance deficits. Opp. at 11. Mr. Kostka contends in response that his gap in treatment was reasonable due to the COVID-19 pandemic. Additionally, the appointments cited by Respondent were for unrelated medical issues, some of which significant including chronic obstructive pulmonary disease, sepsis, and respiratory failure. Opp. at 10. I also note that the COVID-19 Pandemic began in March 2020, and is a reasonable explanation for why treatment visits may have ceased prior March 19, 2020.

The overall record thus constitutes a sufficient showing of severity to meet the preponderance evidentiary standard. It is likely that Mr. Kostka's symptoms persisted through March 19, 2020, despite the cessation of treatment one week earlier. Nevertheless, his reports of mild pain, evidence that he made significant and swift progress, and the fact that he appears to have been close to recovery at the six-month post-onset mark all suggest the existence of a mild injury – and damages to be awarded in this case will reflect this finding.

B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Mr. Kostka has satisfied the QAI requirements for a Table SIRVA.

1. Mr. Kostka Had No Prior Left Shoulder Condition or Injury that would Explain his Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Mr. Kostka meets this criterion, and I find that he has demonstrated a lack of history of pain, inflammation, or dysfunction of his left shoulder that would explain his symptoms.

2. Onset of Mr. Kostka's Injury Occurred within Forty-Eight Hours of his Vaccination

The medical records preponderantly establish onset of injury close-in-time to vaccination. Mr. Kostka first reported shoulder pain five days after his September 19, 2019, vaccination, stating that he had "progressively worsening pain ever since" his flu vaccination. Ex. 11 at 46. Thereafter, Mr. Kostka continued to link his shoulder pain temporally to the flu vaccine. See Ex. 2 at 461 (record from September 27, 2019, stating that Mr. Kostka got a flu vaccine and "pain in his shoulder has been bad"); Ex. 11 at 15 (record from October 2, 2019, stating his pain started after a flu shot on September 19, 2019).

Respondent argues that Mr. Kostka's statements are vague and inconsistent, with records indicating his pain began at various times including before his vaccination. Opp. at 14-16. Even so, a finding of proper onset can be made based on such a record. Program petitioners are not required to marshal records setting forth with chronographic specificity the precise day and hour that their onset manifested. Further, as noted above, Mr. Kostka consistently linked his shoulder pain to the September flu vaccine.

Additionally, the relevant medical records show that Mr. Kostka reported shoulder pain in a relatively timely manner, when measured from the date of vaccination. Thus, Mr. Kostka first began to complain of shoulder pain within five days of the vaccine and did not attribute his pain to any other injury or cause.

Respondent also argues that Mr. Kostka failed to report shoulder pain on September 23, 2019, when he was seen for a consultation relating to his interstitial lung disease, undermining his assertion that symptoms began within forty-eight hours of the vaccination. Opp. at 17-18. But it is not unexpected that Petitioner did not raise his shoulder pain on September 23rd, as that appointment was for a specific and unrelated issue. Ex. 1 at 134-35. Further, it is common for SIRVA petitioners to delay seeking treatment, thinking the injury will resolve on its own, especially since patients are often

told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. And individuals also often misconstrue the nature of their injury, and therefore fail to inform treaters of all specific facts relevant to onset until later. Here, the added detail of onset did not “wait” for months before being provided, but began to be reported in a reasonable time post-vaccination.

Accordingly, there is preponderant evidence that establishes the onset of Mr. Kostka’s left shoulder pain more likely than not occurred within 48-hours of vaccination.

3. Mr. Kostka’s Pain was Limited to his Left Shoulder

Mr. Kostka’s pain was limited to his left shoulder. Respondent does not contest this aspect of Mr. Kostka’s claim, and there is nothing in the records to suggest otherwise.

4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner’s current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Mr. Kostka’s claim, and there is nothing in the records to suggest that any such condition or abnormality exists.

C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Mr. Kostka has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Mr. Kostka received a flu vaccine intramuscularly on September 19, 2019, in the United States. Ex. 7 at 2; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Mr. Kostka has collected a civil award for his injury. Ex. 1; Section 11(c)(1)(E) (lack of prior civil award).

Based upon all of the above, Mr. Kostka has established that he suffered a Table SIRVA. Additionally, he has satisfied all other requirements for compensation. I therefore find that Mr. Kostka is entitled to compensation in this case.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Mr. Kostka satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Mr. Kostka is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master